GOVERNMENT OF INDIA
CHEMICALS AND FERTILIZERS
LOK SABHA

UNSTARRED QUESTION NO:3316
ANSWERED ON:10.12.2002
SETTING UP OF NATIONAL DRUG AUTHORITY
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Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

(a) whether Hathi Committee long back even before the formulation of the first Drug Policy of1978 had recommended the setting of the National Drug Authority;

(b) if so, the reasons for not acting upon the recommendations of the Hathi Committee and the measures Government propose to take to expedite the establishment of the Authority;

(c) whether in the absence of the Authority, the objectives of National Drug Policy as well as National Heath Policy are meaningless; and

(d) if so, the reaction of the Government thereto?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF CHEMICALS & FERTILIZERS (SHRI TAPAN SIKDAR)

(a) to (d): The (Hathi) Committee on Drugs and Pharmaceuticals Industry, in its reportsubmitted inApril,1975, had, interalia, recommended the setting up of a National Drug Authority − an autonomous body which would handle all matters concerning the future expansion of the drug industry licensing, imports, exports technological development. Government laid a Statement on the Table of the Lok Sabha on 29.3.1978 containing its decisions on the said recommendations (later known as Drug Policy,1978) wherein it was concluded that it would not be possible to establish a totally independent authority on the lines suggested by the Committee. However, it was approved to set up a field organisation in the Department of Chemicals & Fertilizers under a Development Commissioner (Drug Industry).
The Government reviewed the Drug Policy,1978 and restructured it in 1986 byannouncing`Measures for Rationalisation, Quality Control and Growth of Drugs & PharmaceuticalIndustry in India` which, interlaia, envisaged setting up of a machinery to be called the National Drug and Pharmaceuticals Authority to look after the rational use of drugs.The importance of quality control and rational use of drugs was reiterated in the `Modifications in Drug Policy,1986` , announced in September,1994 and it was envisaged therein that a National Drug Authority be set up to undertake the regulatory functions performed by the Central Drugs Standard Control Organisation (CDSCO) in addition to assuming many new responsibilities. This, interalia, required major structural changesin the existing regulatory system, where licensing of manufacturers etc. as well as enforcement of the Drugs & Cosmetics Act,1940 and Rules made thereunder, are primarily done by the state authorities. Efforts are being made to strengthen the existing capacity of the Central Drugs Standard Control Organisation (CDSCO) which would be necessary before undertaking the new responsibilities.